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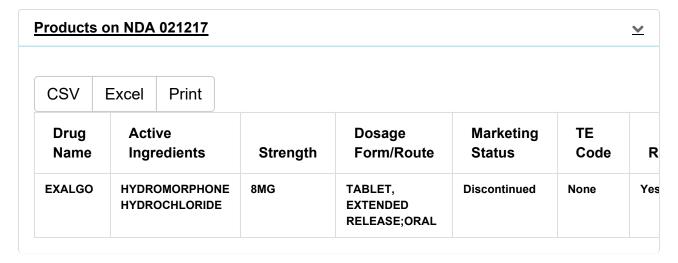
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New Drug Application (NDA): 021217

Company: SPECGX LLC

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- Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021217s023s024lbl.pdf#page=30)
- REMS (http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm? event=RemsDetails.page&REMS=17)
- Summary Review (http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/021217s000SumR.pdf)



Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	R
EXALGO	HYDROMORPHONE HYDROCHLORIDE	12MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes
EXALGO	HYDROMORPHONE HYDROCHLORIDE	16MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes
EXALGO	HYDROMORPHONE HYDROCHLORIDE	32MG	TABLET, EXTENDED RELEASE;ORAL	Discontinued	None	Yes

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Approval Date(s) and History, Letters, Labels, Reviews for NDA 021217

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Original Approvals or Tentative Approvals

CSV	Ех	cel	Print					
Action Date		Su	bmissioi	n	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Review
03/01/201	10	ORIO	G-1		Approval	Type 3 - New Dosage Form	STANDARD	Label (PDF) (https Letter (PDF) (https Review (https://wv Summary Review

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Supplements

CSV	E	cel	Print		
Action Date	n	Su	bmission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
09/18/2018	SUPPL-24	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc
09/18/2018	SUPPL-23	REMS - MODIFIED - D-N-A	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc
05/26/2017	SUPPL-21	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc
12/16/2016	SUPPL-19	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/dru Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc
09/30/2016	SUPPL-20	REMS - MODIFIED - D-N-A	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_dod
04/20/2016	SUPPL-17	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc
06/26/2015	SUPPL-15	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_dod
06/02/2015	SUPPL-9	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/dru Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_doc

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package
08/19/2014	SUPPL-14	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_do
06/17/2014	SUPPL-12	Labeling- Medication Guide, REMS- Proposal, Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/drugsatfda_do Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_do
04/16/2014	SUPPL-13	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/dr Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_do
04/15/2013	SUPPL-6	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_do
03/18/2013	SUPPL-5	Labeling- Package Insert	Label (PDF) (https://www.accessdata.fda.gov/dr Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_dd
08/24/2012	SUPPL-4	Labeling- Package Insert, REMS-Modified	Label (PDF) (https://www.accessdata.fda.gov/di Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_do
07/09/2012	SUPPL-2	Labeling, REMS- Modified	Label (PDF) (https://www.accessdata.fda.gov/di Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_do
03/24/2010	SUPPL-1	REMS-Modified	Letter (PDF) (https://www.accessdata.fda.gov/drugsatfda_do

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Labels for NDA 021217

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